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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/392,243      | 09/09/1999  | JOHN H. LEE          | 27338               | 9819             |

164 7590 10/17/2002  
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EXAMINER  
PRATS, FRANCISCO CHANDLER

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1651  
DATE MAILED: 10/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

|                        |                               |                  |
|------------------------|-------------------------------|------------------|
| <b>Advisory Action</b> | Application No.               | Applicant(s)     |
|                        | 09/392,243                    | LEE ET AL.       |
|                        | Examiner<br>Francisco C Prats | Art Unit<br>1651 |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 02 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a)  The period for reply expires 3 months from the mailing date of the final rejection.
- b)  The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b)  they raise the issue of new matter (see Note below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3.  Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4.  Newly proposed or amended claim(s) \_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5.  The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7.  For purposes of Appeal, the proposed amendment(s) a) will not be entered or b) will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 21-27 and 36-54.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8.  The proposed drawing correction filed on \_\_\_\_ is a) approved or b) disapproved by the Examiner.
9.  Note the attached Information Disclosure Statement(s) ( PTO-1449 ) Paper No(s). \_\_\_\_\_.
10.  Other: \_\_\_\_\_.

Francisco C Prats  
Primary Examiner  
Art Unit: 1651

**ATTACHMENT TO ADVISORY ACTION**

The after final amendment filed October 2, 2002, has been received and will be entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

All of applicant's argument submitted October 2, 2002, has been fully considered, but is not persuasive of error.

With respect to the rejection under § 112, second paragraph, it is respectfully submitted that claim 42 still does not make sense. While it may be true that eventually the hydrogen peroxide added to the mucosa decomposes, it is simply impossible to add peroxide to the mucosa and then detect no peroxide immediately thereafter. Because of this impossibility, as drafted, the claim makes no sense.

With respect to the rejection under § 103(a), note specifically that at bottom, applicant's claims are directed to adding known preservative agents to a material, mucosa, which is disclosed by the prior art as benefiting from the presence of preservatives. Absent some demonstration of an unexpected result, the claims must be considered obvious.

Applicant's assessment, that the heating and preservative addition steps of Van Gorp are mutually exclusive, is incorrect. By disclosing that either heating or preservative addition is

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suitable to ensure low microorganism counts in the mucosa preparations, Van Gorp clearly provides a reasonable expectation that using both methods will provide a beneficial result as well, thereby rendering such a practice obvious. Note that these methods of spoilage prevent are extremely well known and extremely old in the art of preservation. Moreover, if this combination of steps is required or critical for patentability, it should appear in the independent claim, not in one of the dependent claims.

Applicant's argument regarding Van Gorp's failure to disclosure hydrolysis of the mucosa ignores the plain disclosure of the reference. The title of the Van Gorp patent is "Protein Hydrolysate Derived From Mucosa Tissue." The abstract states that mucosa tissue is hydrolyzed with a proteolytic enzyme. Enzymes are protein-containing materials. Because the claimed starting material is contacted with the claimed treating agent, the result, reduction of enzymatic activity, must necessarily be the same. If the result is not the same, the difference must be due to some aspect not currently recited in the claims.

Also, it is not clear how the prior art-suggested addition of peroxide or phosphoric acid to mucosa would not yield the claimed "preserved mucosa tissue." The prior art clearly suggests adding the claimed preserving agents to the claimed

starting material. If there is some difference between the claimed "preserved mucosa tissue" and the product resulting from adding peroxide or phosphoric acid to mucosa, applicant has not demonstrated the difference.

Further still, the assertion of equivalence between Van Gorp's preservatives and those of Balslev and Oles is based on the disclosure of the prior art, not on conclusory statements. The preservative activities of peroxide and phosphoric acids are well known. See Balslev and Oles. Thus, based on the cited references, one of ordinary skill would have reasonably expected the two claimed preservative agents to have inhibited microbial growth when applied to Van Gorp's mucosa preparation. In the sense that peroxide and phosphoric acid are disclosed by Balslev and Oles to be useful to inhibit bacterial growth in food applications, peroxide and phosphoric acid are in fact equivalent to Van Gorp's preservatives. While Exhibit A demonstrates that many different preservatives can be used in many different food applications, the very disclosure by Exhibit A of the many and varying applications of preservatives demonstrates that it would have been routine in the art to determine which preservatives would have been suitable for use in Van Gorp's mucosa preparation.

Lastly, regarding the alleged teaching away from the combination of Van Gorp's enzymes and Balslev's peroxide based on the supposed inactivation of the enzymes by the peroxide, note again that the preservative in Van Gorp is to be added to the mucosa prior to storage, and that Balslev clearly discloses that the peroxide content ultimately reduces to nothing. Thus, there is no clear teaching away. Moreover, applicant has not demonstrated through direct evidence that the peroxide concentrations of Balslev would in fact have inhibited Van Gorp's proteolytic enzymes. Thus, to the extent it is not based on facts on the record, it is applicant's argument which is technically speculative in this regard.

In sum, it is again pointed out that at bottom, applicant's claims are directed to adding known preservative agents to a material, mucosa, which is disclosed by the prior art as benefiting from the presence of preservatives. Because applicant has presented no evidence of any unexpected result, the claims must be considered obvious.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco

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C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
October 16, 2002